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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,708	06/16/2006	Stefan Bracht	RO4101US	5800

7590 06/08/2011

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
06/08/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,708	BRACHT, STEFAN	
	Examiner	Art Unit	
	Isis Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *5-8,11 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,9,10,12-14 and 16-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's amendment after final filed 01/24/2011 and request for RCE filed 02/22/2011.

Claims 1-20 previously presented.

Claims 5-8, 11, 15 are withdrawn from consideration as being drawn to nonelected invention. Election was made with traverse in the reply filed on 03/15/2010.

Claims 1-4, 9, 10, 12-14, 16-20 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/22/2011 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-4, 9, 10, 12-14, 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Degen (DE 10053375, of record) as optionally evident by the provided articles: "4-aminobenzoic acid", encyclopedia, "CINNAMIC ACID", product identification, "Benzophenone", IngredientsFeedbackScience, and "Lacquer definition", Your Dictionary, and in view of Godbey et al. (US 5,372,819, currently listed on PTO 892).

Applicant Claims

Applicant's claim 1 is directed a medical active substance patch comprising a matrix of monolayer or multilayer configuration and a backing layer connected with said matrix, said backing layer having one side averted from the skin, wherein at least one layer of the matrix contains a pharmaceutically active substance, and wherein at least one layer of the matrix contains an ingredient selected from the group consisting of at least one coloured ingredient, and at least one colourless ingredient being colourless in an initial state and tending to discolour or to discolour(s) during storage or to discolour

during the application period, and wherein said at least one coloured ingredient and said at least one colourless ingredient are selected from the group consisting of a pharmaceutically active substance and an auxiliary agent; said active substance patch being transparent or translucent; said active substance patch comprises at least one substance selected from the group consisting of dyes and pigments in at least one of said layers; in the state of having been applied to a first person's skin said patch, at a place of the skin covered with the patch, has a lightness colour value L_1 which is not less than 50% and not more than 200% of a lightness colour value L_2, with L_2 being the lightness value of the region of the skin of the same person which surrounds the applied patch, and that the same applies in respect of the skin of a second or any other person, provided that L_2 is in the range from 5° to 100°.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Degen teaches transparent transdermal therapeutic system (TTS) contain photosensitive active ingredient. The TTS comprises colorless active ingredients contained in polymer matrix and has a backing layer. The matrix and the backing comprise UV absorbent that does not have pharmacological or therapeutic effect. UV absorbent are homogeneously distributed as dissolved or dispersed form in the matrix and in the backing layer. Photosensitive active ingredient is nicotine. TTS has a transparent backing layer and a transparent active substance matrix therefore little noticeable during application to the skin. TTS provides protection of the photosensitive

active ingredients against light decomposition. Transparent backing materials are preferably polyester, polyethylene, polypropylene, polyurethane, ethyl Vinyl acetate, or polyethylene terephthalate (PET), as those used by applicant. Matrix materials of the TTS are preferably polyacrylates, polyisobutylenes, polydimethylsiloxanes, or styrene-isoprene-block copolymers, as those used by applicant. Preferred UV absorber is present in amount of 5-10%, and present invention used 7.75% according to table 1. UV absorber includes p-aminobenzoic acid and its derivatives, cinnamic acid and its derivatives, and benzophenones. UV absorbers disclosed by the reference may read on dyes or pigments since all of them have color (white) as evident by the provides articles: "4-aminobenzoic acid", encyclopedia; "CINNAMIC ACID", product identification; and "Benzophenone", IngredientsFeedbackScience. TTS can be multilayered. TTS applied to the skin and remains there for a long period, for example some hours to several days.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Although Degen teaches UV absorbent in the backing layer to protect the photosensitive drug, and although UV absorbent having color, however the reference does not explicitly teach pigment or dye in the backing layer.

Godbey teaches transdermal patch comprising backing layer that may be transparent and preferably contains pigments (col.2, lines 35-40; col.4, lines 30-35; examples 37-40).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal patch having backing containing UV absorbent as taught by Degen and replace the UV absorber by pigment or further add pigment to the backing as taught by Godbey. One would have been motivated to do so because Degen desired to protect the transdermal patch from light by adding UV absorber and because Degen preferred to add pigment to the backing for the same purpose. One would reasonably expect formulating transdermal patch having backing comprising pigment that successfully protect photosensitive active agent in the patch.

Regarding the claimed lightness color value claimed by claim 1 and numeric values claimed by claim 17, such properties are intrinsic properties of the patch taught by Degen combined with Godbey because the combination of the references teaches patch has the same structure and made from the same materials used by applicant. Further, regarding testing of the patch to determine the lightness color value and the method of testing as claimed by claim 16, these are not part of the claimed transdermal patch. It is only an in-vitro diagnostic test that is expected to provide the same results obtained from two similar transdermal delivery devices built from the same materials and tested under the same circumstances, and the recitation of this in-vitro test does not impart patentability to claims directed to transdermal device. The burden is on applicants to show that the claimed testing process resulted in novel and unobvious difference between the claimed product and prior art product since the Patent Office

does not have the facilities for preparing the claimed materials and comparing them with the prior art inventions. See *In re Best*, 562 F.2 1252, 195 USPQ 430 (CCPA 1977); and *In re Fitzgerald et al.*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Regarding coating of the dye or pigment on the backing layer as claimed by claim 4 using lacquer as claimed by claim 13, Degen teaches homogenous distribution or solvating the UV absorber in the backing material, and homogenous distribution will provide UV absorber on the surface of the backing forming coating. Lacquer is nothing but solvent, as evident by the definition provided from "Your Dictionary", and solvating the UV absorber in a solvent before application to the backing reads on lacquer claimed by claim 13.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

5. Applicant's arguments with respect to claims 1-4, 9, 10, 12, 14, 16-20 have been considered but are moot in view of the new ground(s) of rejection under 35 U.S.C. 103(a) as being unpatentable over Degen in view of Godbey.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571)272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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